

Remarks

Claims 1-8 and 32-43 are pending in this application. No claims amendments are made in this paper, and no new matter has been introduced. Applicants appreciate the Examiner's withdrawal of the rejection under 35 U.S.C. § 102. However, Applicants respectfully submit that the pending claims are allowable for at least the reasons stated below.

The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

On pages 2-3 of the Office Action, the rejection of the pending claims under 35 U.S.C. § 103 is maintained. In particular, it is alleged that the claims are obvious over Jeffery *et al.*, *J. Chem. Soc., Perkin Trans.*, 1: 2583-9 (1996) ("Jeffery") because Jeffery discloses racemic mixtures of certain compounds whose stereoisomers are encompassed by claim 1. In the Examiner's words:

[t]he expectation with regard to enantiomers is that activities as they pertain to living system are expected to be different ... The fundamentals of optical activity and stereoisomerism are well known to person having ordinary skill in the art. A person having ordinary skill in the art would have known how to resolve the racemic mixture and would have been motivated to do so with the reasonable expectation of achieving enantiomers having substantially different pharmacological activity.

Office Action, page 2. For support, the Examiner cites to *In re Adamson*, 275 F.2d 952 (C.C.P.A. 1960). Applicants respectfully traverse this rejection.

It is well-settled that three basic criteria must be met to establish a case of *prima facie* obviousness: first, there must have been at the time of the invention a motivation to combine the references cited; second, the alleged prior art must teach or suggest all of the limitations of the claims alleged to be obvious; and third, there must have been at the time of the invention a reasonable expectation of success. Manual of Patent Examining Procedure ("MPEP"), § 2142. In addition, a *prima facie* case of obviousness may be rebutted by showing that the claimed invention achieves unexpected results or by showing that the art teaches away from the claimed range. MPEP § 2144.05(III) (emphasis added).

As Applicants previously pointed out in their response filed April 12, 2004, a *prima facie* case of obviousness cannot be established by Jeffery. Specifically, Applicants provided that: 1) Jeffery fails to teach the stereoisomers of the claimed compounds; and 2) Jeffery would not have provided those of ordinary skill in the art with the motivation to make and use the claimed compounds because Jeffery discloses that the pharmacological activity of sibutramine is mediated predominantly by sibutramine metabolites other than those claimed in this application. Response of April 12, 2004, page 7. The Examiner does not provide any evidence or arguments to refute these arguments. Instead, the Examiner, relying on *In re Adamson*, essentially alleges that a stereoisomer of a compound whose racemic mixture's structure and activity are known cannot be patented *per se*. This is directly contrary to legal precedent.

As well-established, "a novel chemical compound can be non-obvious to one having ordinary skill in the art notwithstanding that it may possess a known property in common with a known structurally similar compound." *In re Albrecht*, 514 F.2d 1389, 1395-6 (C.C.P.A. 1975) (emphasis in original). Instead, "those properties which have been expected must be balanced against the unexpected properties." *In re May*, 574 F.2d 1082, 1094 (C.C.P.A. 1978). Applicants respectfully submit that sufficient unexpected properties are shown in this application to rebut the *prima facie* case of obviousness, if required.¹ This is because Jeffery actually teaches away from the claimed compounds by disclosing that the racemic mixture of claimed compounds do not contribute to the activity of sibutramine.

Furthermore, Applicants respectfully submit that the Examiner's reliance on *In re Adamson* is misplaced. *In re Adamson* concerned claims directed to an L-isomer of a chemical compound having substantially higher spasmolytic activity than the D-isomer of the same compound. *In re Adamson*, 275 F.2d at 952-953. The spasmolytic activity and structure of the compound were disclosed in the prior art. *Id.* at 953. To the contrary, the pharmacological activity of the claimed compounds is not disclosed in Jeffery. In fact, Jeffery teaches that the claimed compounds are likely to be pharmacologically inactive. Therefore, Applicants respectfully submit that the principles of *In re Adamson* are not applicable in this application.

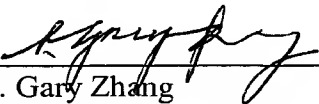
¹ Applicants again expressly submit that no *prima facie* case of obviousness has been established in this application for at least the reasons stated above.

Consequently, Applicants respectfully submit that all of the pending claims are allowable, and request that the rejection of the pending claims under 35 U.S.C. § 103 be withdrawn.

No fee is believed due for this submission. Should any additional fees be due for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

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